

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number : 10/808,553 Confirmation No.: 4926
Applicant : Vincent Bryan *et al.*
Filed : March 25, 2004
Title : DRILL HEAD FOR USE IN PLACING AN INTERVERTEBRAL
DISC DEVICE
TC/Art Unit : 3733
Examiner: : Jerry L. Cumberledge

Docket No. : MED-017 D1
Customer No. : 71998

DECLARATION OF CARLOS GIL

I, Carlos Gil, hereby declare and state as follows:

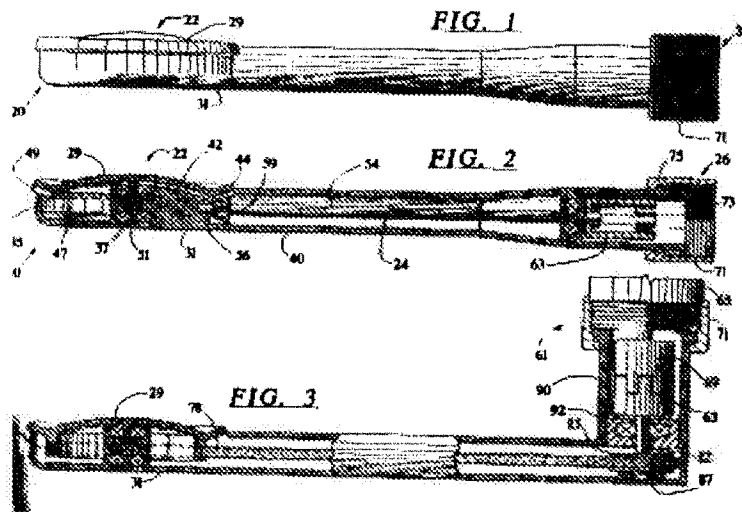
1. I am a citizen of the United States residing at 1707 Powell Run Cove, Collierville, TN 38017.
2. My educational background includes a Bachelor of Science in Engineering Technology in 1986 from the University of Memphis, located in Memphis, Tennessee, and an Associate of Science in Mechanical Engineering in 1982 from the State Technical Institute located in Memphis, Tennessee.
3. I have been in the medical orthopedic industry for over 20 years. Most of my work has been in the development of orthopedic implants and associated instruments for use in hip, knee, shoulder, spine, foot, and finger surgery. The vertebral body milling apparatus which is disclosed and claimed in the application identified in caption is the type of device that I have worked with and developed for most of my professional career.
4. Since 1999, I have served as Director of Product Development for Medtronic Sofamor Danek, an Indiana Corporation located at 2600 Sofamor Danek Drive, Memphis,

Tennessee 38132 ("Medtronic"). Medtronic is a wholly-owned subsidiary of Medtronic, Inc., a Minnesota Corporation located at 710 Medtronic Parkway, Minneapolis, MN 55432. Warsaw Orthopedics, Inc., is a wholly-owned subsidiary of Medtronic, and Warsaw Orthopedics, Inc. is the assignee of the present patent application, Serial No. 10/808,553 ("the '553 application"). My current title is Senior Principal Research and Development Engineer.

5. I have reviewed the present application in its entirety and I am familiar with its teachings. I consider myself to be a person having at least ordinary skill in this art, and I am qualified to opine as to how a person of ordinary skill in the art would read and understand prior art to the present application.

6. The present application discloses and claims a "drill head for preparing the bone of two vertebral bodies to accept the concaval-convex shape of an endoprosthesis." *See*, Abstract. The claimed device includes a shaft, a drive mechanism, a power source operably connected to the drive mechanism, and an abrading element. The device prepares a space in the human spine to receive an insert between adjacent vertebral bodies, and the abrading element has an abrading surface that forms a surface contour in one of the adjacent vertebral bodies as the abrading element is moved by the drive mechanism. Accordingly, the device has a profile that allows the abrading element to fit in the narrow space between two opposing vertebral bodies in the cervical spine of a patient, and at the same time form a contour in one of the adjacent vertebral bodies.

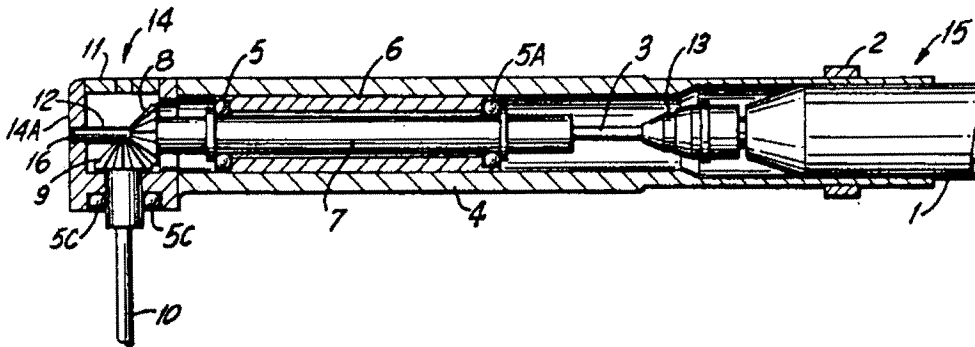
7. Figures 1-3 of the '553 application are reproduced as follows:



8. I understand that the pending claims of the present application have been rejected by the United States Patent Office as anticipated by, or rendered obvious over, United States Patent No. 5,041,119, entitled "Angular Attachment for Drill," and issued to Frigg, *et al.*, in 1991 (the "Frigg patent"). The specific rejections are contained in a December 3, 2007 Final Office Action, which I have read in its entirety. I also have read the Frigg patent in its entirety and I am familiar with the devices disclosed and claimed therein.

9. The Frigg patent, in contrast to the present application, relates to an angular drilling attachment for use in surgical procedures, whereby the position of the metallic drill bit is monitored by X-radiation. *See* Summary of the Invention section of the Frigg patent. The various embodiments disclosed in the Frigg patent include conventional or hollow drill bits inserted over a guide wire that can be used, for example, on the spinal column or the pelvis, where bone screws must be set with extreme precision (*See*, column 2, lines 15-23 of the Frigg patent). The drill bits are elongated and used to form a hole in a bone for insertion of a bone screw. *See* Figure 1 of the Frigg patent.

10. Figure 1 of the Frigg patent is reproduced below:



11. Based on my years of experience in developing and testing vertebral body milling apparatus and methods of the type disclosed and claimed in the present application, the device disclosed in the Frigg patent, including the device shown above in Figure 1, does not contain all of the structural limitations of the present claims. For example, the device disclosed in the Frigg patent does not include at least the following elements recited in the claims:

- a) an apparatus "for preparing a space in the human spine to receive an insert between adjacent vertebral bodies." (See Claim 49);
- b) "an abrading element having at least one abrading surface selected to create a predetermined surface contour in an end plate of one of the adjacent vertebral bodies in the narrow space between two opposing vertebral bodies." (See Claim 49);
- c) "an abrading element having at least one convex abrading surface selected to create a concaval-convex contour in one of the adjacent vertebral bodies." (See Claim 130);

12. In addition, none of the devices disclosed in the Frigg patent could be used to perform like the devices disclosed and claimed in the present application. For example, the devices disclosed in the Frigg patent could not achieve the stated objective of the present

application, namely the development of an apparatus that could be used to drill in-between adjacent vertebral bodies. Indeed, given the sensitive nature of the human spine, it is *impossible* to use the devices described in the Frigg patent to achieve the device structure and functionality disclosed and claimed in the present application.

13. The August 22, 2003 Final Office Action does not expressly describe how the Frigg device includes the claim recitations (a)-(c) listed above in paragraph (11). I note only two potential interpretations of how the device described in the Frigg patent might be used to, for example, meet the claim recitations set forth in (a)-(c) listed above, for example, to have a surface that removes bone in an end plate of an adjacent vertebral body to create at least one surface having a predetermined contour. In one interpretation, the drill bit of the Frigg (shown as 10 in Figure 1, for example) enters the area between two adjacent vertebral bodies in perpendicular fashion. In a second interpretation, the drill bit enters in parallel relation to the vertebral end plate surfaces; that is, the length of drill bit 10 would be parallel to the surfaces of the vertebral bodies. Notably, neither approach provides a cutting surface as described and claimed in the present application. Indeed, any effort to do so would expose a patient to life-altering and or life-threatening injuries.

14. Inserting any of the Frigg device drill bits perpendicularly into a space between two vertebral bodies — essentially as shown in Frigg Figure 1 shown above — would not work given the narrowness of that space. The inventors of the present application state in the specification that the distance between adjacent vertebral bodies is approximately nine millimeters. *See*, '553 Application, and claim 124. The Frigg patent, on the other hand, includes no disclosure that would suggest its device could fit between adjacent vertebral bodies, and in fact, suggests just the opposite. The Frigg patent explicitly states that the drill described therein

can be used to prepare a space “where bone screws must be set with extreme precision.” (col. 2, lines 21-23 of the Frigg patent). Bone screws are not set between vertebral bodies. Rather, bone screws are set within the vertebral body itself — typically in the pedicle of the vertebral body. As is well known, these screws are used to fix plates, rods, and other fixation devices to the vertebral body. Accordingly, one could not even enter the inter-vertebral space, let alone cut a shape into an end plate of an adjacent vertebra to create a space between the vertebral bodies to accept an insert.

15. The other interpretation, (*i.e.*, providing the drill bits of the Frigg patent parallel to a surface the disc space), fares no better. In essence, while using this approach might permit insertion of the drill bit in the inter-vertebral disc space, the Frigg device does not provide, as is required by the present claims, a surface that creates a surface contour in an end plate of an adjacent vertebral body, and certainly could not be used to create at least one surface having a predetermined contour in an end plate of at least one adjacent vertebral body. When placed on the surface of an end plate of a vertebral body, when inserted in this manner, the tendency of the Frigg device’s drill head would be to roll off, much like a wheel does when coming in contact with a hard, solid surface. This lack of control essentially renders the Frigg device a useless (and potentially life threatening) instrumentality for performing the type of spinal surgery contemplated by the claimed invention. More importantly, such lack of control means that the Frigg device does not provide, as does the claimed invention, a space between adjacent vertebral bodies to receive an insert.

16. In view of the above, it is my opinion that the device disclosed by Frigg does not provide a milling surface enabling the formation of a predetermined shape on an adjacent vertebral body, as does the device according to the present invention.

17. I further declare that all statements made herein are based on personal knowledge or upon information and belief and are believed to be true; and further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

CARLOS GIL

A handwritten signature in black ink, appearing to read 'Carlos Gil', written over a horizontal line.

Carlos Gil
Director of Product Development
Medtronic Sofamor Danek

Dated: February 9, 2008